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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/600,070

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Katherine W. Osteryoung

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EXAMINER

KUBELIK, ANNE R

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/600,070	<b>Applicant(s)</b> OSTERYOUNG ET AL.	
	<b>Examiner</b> Anne R. Kubelik	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 23-42 is/are pending in the application.
- 4a) Of the above claim(s) 35-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 29 October 2007 has been entered.
2. Claims 23-42 are pending. Claims 35-42 are drawn to sequences nonelected in the response filed 23 May 2005. Thus, claims 35-42 are withdrawn from consideration as being drawn to a nonelected invention.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. In the response filed 29 October 2007, Applicant requested that the finality of the Office action mailed 18 October 2007 be withdrawn because they have pursued prosecution in good faith and have not engaged in behavior to prolong examination.

This is not found persuasive because relative to the non-final Office action mailed 14 May 2007 there were no new rejections that were not due to Applicant's amendment. Applicant's good faith is not a not reason for the examiner to reply with a second non-final rejection.

Applicant urges that claims 27-30 should have been allowed due to their mistaken inclusion in the enablement rejection, depriving Applicant of their opportunity to obtain a patent and file a continuation before Nov. 1.

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This is not found persuasive because the specification does not teach how to use plants in which Ftn2 is overexpressed. The phenotype of such plants is not taught; thus one of skill in the art would not know how to use them. See the enablement rejection on pg 7 of the action mailed 18 October 2007, as well as on pg 6 of the non-final rejection mailed 14 May 2007, pg 6 of the final rejection mailed 10 August 2006 and pg 7 of the non-final rejection mailed 3 March 2006.

5. The rejection of claims 23-26 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for new matter is withdrawn in light of Applicant's amendment of the claims.

6. The rejection of claim 29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is withdrawn in light of Applicant's amendment of the claims.

#### ***Claim Rejections - 35 USC § 112***

7. Claims 23-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid encoding SEQ ID NO:2, does not reasonably provide enablement for a vector comprising any nucleic acid that is at least 90% homologous to SEQ ID NO:1 or 3, wherein the nucleic acid encodes a product that functions in photosynthetic prokaryote or plastid division, or for cells, plants and seeds transformed with a nucleic acid encoding SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Due to Applicant's amendment of the claims, the rejection is modified from the rejection set forth in the Office action mailed 18 October 2007, as

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applied to claims 23-30. Applicant's arguments filed 29 October 2007 have been fully considered but they are not persuasive.

The claims are broadly drawn to a vector comprising an *Arabidopsis* nucleic acid encoding an Ftn2 protein or a vector encoding SEQ ID NO:2 and plants or cells comprising the latter vector.

The instant specification describes the isolation of Ftn2 from *Synechococcus* and identification of putative cyanobacterial homologs (examples 4 and 5), which has 17% identity to an unknown protein (SEQ ID NO:2, encoded by the genomic sequence SEQ ID NO:3 and cDNA SEQ ID NO:1) in *Arabidopsis*; mapping the *arc6* mutation in *Arabidopsis* to show that it and the unknown protein map to chromosome 5 (example 2); rescuing the *arc6* mutation by SEQ ID NO:1 (example 2); analysis of the mutant to show that FtsZ rings and filaments are disrupted (example 2); identification of potential Ftn2 homologues from various database sequences (example 3); isolation of an Ftn2 gene from *Synechococcus* by transposon mutagenesis (examples 4-5); identification of *arc5* (examples 6) and Fzo-like (example 7) genes from *Arabidopsis*. The specification teaches that SEQ ID NO:2 does not have a proper DnaJ domain or a complete myb domain, but appears to have a chloroplast targeting sequence and three putative transmembrane helices (pg 90-91).

The instant specification fails to teach how to make the full scope of *Arabidopsis* nucleic acids encoding an Ftn2 protein.

There are at least 12 *Arabidopsis* species: *A. arenicola*, *A. arenosa*, *A. cebennensis*, *A. croatica*, *A. halleri*, *A. kawasakiana*, *A. lyrata*, *A. neglecta*, *A. pedemontana*, *A. petrogena*, *A. suecica* and *A. thaliana*. The specification only teaches the a sequence from *A. thaliana*, SEQ ID

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NO:1. It does not teach how to make the sequences from other species.

The specification also does not teach how to use plants in which Ftn2 is overexpressed. The phenotype of such plants is not taught; thus one of skill in the art would not know how to use them.

The specification on pg 16, lines 8-10 states that a decreased amount of Ftn2 results in plant cells with one or few chloroplasts. These plants have an art-established use in plastid transformation. However, at no place does the specification teach how to use plants in which Ftn2 is overexpressed.

Additionally, even 5 years after the filing of the instant application, the function of Ftn2 is not known (Maple et al, Annals Botany 99:565-579; pg 570, right column, paragraph 2). Also, Arc6 (the instant SEQ ID NO:2) appears to have a very different function in plants than Ftn2 does in prokaryotes (pg 570, right column, paragraph , to pg 571, right column, paragraph 2).

Given the claim breath, unpredictability in the art, undue experimentation, and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

Applicant urges that claims 27-30 are mistakenly included in the rejection as they recite SEQ ID NO:2 (response pg 4).

This is not found persuasive because while the specification is enabled for making a nucleic acid encoding SEQ ID NO:2, it does not teach how to use a plant transformed with a nucleic acid that encodes it.

Applicant urges that the previous office action stated that the specification teaches the

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identification of potential Ftn2 homologues from various database sequences, and these were the basis for the amino acid positions in the previous version of the claims; these are common core sequences, as shown in the Table in Applicant's response (response pg 4-5).

This is not found persuasive they have no relevance to the instant claims. They and the specification also fail to teach how to make the full scope of Arabidopsis nucleic acids encoding an Ftn2 protein.

Applicant urges that the specification teaches *Synechococcus* and rice sequences (response pg 6).

This is not found persuasive because neither of these teaches how to make the full scope of Arabidopsis nucleic acids encoding an Ftn2 protein.

Applicant urges that the specification teaches that plants transformed with a gene encoding Ftn2 have changed phenotypes, including changed plastid size, number per cell and shape (response pg 6).

This is not found persuasive because plants with a decreased amount of Ftn2 results in plant cells with one or few large chloroplasts, which can be used in plastid transformation. Plants in which Ftn2 is overexpressed would have a large number of small chloroplasts. How does one use such plants?

5. Claims 23-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Due to Applicant's amendment of the claims, the rejection is modified from the rejection set forth in the Office action mailed 18 October 2007, as applied to claims 23-26. Applicant's arguments filed 29 October 2007 have been fully considered but they are not persuasive.

The essential feature of the claims is an *Arabidopsis* nucleic acid encoding an Ftn2 protein. As the protein of SEQ ID NO:2 and its activity are novel, there is no well-developed field of prior art.

The specification describes FTN2 function as a protein that when its levels are decreased leads to incomplete or no division of a prokaryote or plastid, resulting in long filamentous cells in cyanobacteria and single or few very large chloroplasts in plants (pg 15, lines 1-10).

The specification describes Ftn2 proteins as having a DnaJ-like domain at its N-terminal half, but that this domain is missing the essential central HPD motif (pg 60, lines 7-10; pg 90, lines 12-17). Other motifs are described (pg 60, lines 11-20; pg 90, lines 17-27; Table 7), but such motifs are not present in every protein indicated to be an Ftn2 homolog.

There is no description of the structure required for the recited function, and no description of the necessary and sufficient structural elements of a protein with Ftn2 function.

There are at least 12 *Arabidopsis* species: *A. arenicola*, *A. arenosa*, *A. cebennensis*, *A. croatica*, *A. halleri*, *A. kawasakiana*, *A. lyrata*, *A. neglecta*, *A. pedemontana*, *A. petrogena*, *A. suecica* and *A. thaliana*. The specification only teaches the a sequence from *A. thaliana*, SEQ ID NO:3.

The only species described in the specification are SEQ ID NO:3 from *A. thaliana*. The sequences from other species are not described.

One of skill in the art would not recognize that Applicant was in possession of the



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necessary common attributes or features of the genus in view of the disclosed species. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, SEQ ID NO:3 is insufficient to describe the claimed genus.

Hence, Applicant has not, in fact, described *Arabidopsis* nucleic acids encoding Ftn2 proteins within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the claimed compositions, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

Applicant urges that the specification teaches a number of vectors (response pg 7-8).

This is not found persuasive because the rejection is not made because of a lack of description of the vector backbone but because a lack of description of the full scope of *Arabidopsis* nucleic acids encoding Ftn2 proteins.

Applicant makes arguments about the previous claim recitation of particular amino acids of SEQ ID NO:2 (response pg 8).

This is not found persuasive because the instant claims make no such recitation.

Applicant urges that the specification provides a listing of Ftn2 homologs and their accession numbers (response pg 9).

This is not found persuasive because the only *Arabidopsis* sequence described is from *A. thaliana*. There are at least 11 other *Arabidopsis* species: *A. arenicola*, *A. arenosa*, *A. cebennensis*, *A. croatica*, *A. halleri*, *A. kawasakiana*, *A. lyrata*, *A. neglecta*, *A. pedemontana*, *A.*

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*petrogena*, and *A. suecica*.

Applicant urges that *Vas-Cath* states that there is no per se rule that a adequate written description of a biological molecule contains a recitation of a known structure (response pg 9).

This is not found persuasive because Applicant has not described the structural features of *Arabidopsis* sequences from any species other than *A. thaliana*. This is analogous to the situation in *Univ. of California v. Eli Lilly*, where only the rat sequence was taught although sequences from other animals were claimed.

See *Univ. of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997) at pg 1406:

a generic statement such as “vertebrate insulin cDNA” or “mammalian insulin cDNA,” without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.  
... the claimed genera of vertebrate and mammal cDNA are not described by the general language of the '525 patent's written description supported only by the specific nucleotide sequence of rat insulin.

Applicant urges that *Falkner* states that *Lilly* does not set forth a rule that when there is a claim limitation to macromolecular sequence, the specification must describe the sequence of DNAs in the prior art (response pg 10).

This is not found persuasive because the prior art does not teach *Arabidopsis* nucleic acids encoding Ftn2 proteins.

### ***Conclusion***

6. No claim is allowed.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

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Anne Kubelik, Ph.D.  
February 28, 2008

/Anne R. Kubelik/  
Primary Examiner, Art Unit 1638